EXHIBIT 5

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Meeting Record Regarding: Changes to Practice

Date: 6/14/2007

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Materials provided to OMB
Memorandum (85k)
Presentation ((313k)

MEMORANDUM

TO: The Honorable Susan E. Dudley, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

FROM: Derek Minihane, on behalf of the Innovation Alliance

RE: RIN: 0651-AB93
TITLE: Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims ("Continuation Rule")

RIN: 0651-AB94
TITLE: Changes to Practice for the Examination of Claims in Patent Applications ("Claims Examination Rule")

DATE: June 14, 2007

The Innovation Alliance is a coalition of entrepreneurial companies seeking to enhance America's innovation environment and competitiveness through improved patent quality. Our membership list is available at www.innovationalliance.net. The American system for granting patents, in its current form, has permitted incredible innovation allowing high technology and other entrepreneurial businesses to thrive. Innovation by entrepreneurs has been a driving force of this nation's economic success, and great care should be taken in any proposed changes to our patent system that we do not impede this entrepreneurial activity and economic growth.

The above cited draft rules, proposed by the U.S. Patent and Trademark Office ("PTO"), threaten to impose significant limitations on how patent rights are determined in our system. The first proposed rule, the "Continuation Rule," could limit the critical process of dialogue and negotiation with patent examiners that results in many of this nation's most important and innovative patented technologies. The second rule, the "Claims Examination Rule," would set conditions and impose costs that could substantially limit the scope of innovators' claims for patent protection.

The PTO believes that regulatory changes are appropriate to speed up the patent examination process and thereby address the current backlog of patent applications. The backlog is certainly a valid concern, but the "procedural" changes the PTO has proposed here could actually have significantly negative substantive effects. Indeed, both of the PTO's proposed rules have been highly controversial. Even the Administration's own appointed Advisory Council, the Patent Public Advisory Committee of the United States Patent and Trademark Office, has posed strenuous objections to the proposed rules:

> These proposed changes to the practice, taken both individually and together, are troubling in regard to the way they may potentially impact many applicants and their ability to claim an invention in its full scope, as well as the opportunity to fully develop claims of full and proper scope through prosecution with the Office.

See Tab A at 2-3. Many high technology advocates and innovative companies have made very similar specific objections in the record, citing the unintended negative impacts of the proposed rules. Among many others, the National Institutes of Health has expressed "concern that the proposed regulations may disproportionately affect the arts that most directly impact public health…." *See* Tab B at 2.

Likewise, nearly every major association of patent law practitioners has objected to the proposed rules. For example, the *Intellectual Property Owners* association has stated that "we cannot support the proposed rules." *See* Tab C at 1. In addition:

American Bar Association, Section of Intellectual Property Law

> The ABA-IPL opposes the PTO's specific proposals to deal with the current examination crisis, as they do not appropriately address the public's interest in early and final examination of all claims and an applicant's legitimate interest in maximizing the scope of permissible protection. We strongly urge that the new rules not be adopted . . . . (*See* Tab D at 1)

The Bar Association of the District of Columbia

> [T]he *Proposed Continuation Rules* contain many ambiguities and restrictions which will have a detrimental effect on all applicants . . . . Such [a] restrictive approach to prosecution would not foster innovation and will ultimately compromise the public's right to benefit from the progress of science and useful arts. (*See* Tab E at 3-4.)

American Intellectual Property Law Association

> [T]he changes being proposed would not lead to greater efficiency in the examination process, would not reduce the pendency of patent applications, and would not improve the quality of issues patents . . . . Inventors would be far less able to adequately protect their property . . . . AIPLA believes that the proposed changes in continued application practice (and also, to the extent motivated by the same goal, the proposed rule limiting the number of claims to be examined) are the wrong way to attack this problem. (*See* Tab F at 3.)

We agree that the proposed rules will have unintended substantively negative consequences, and we agree with many of the specific objections posed by hundreds of practitioners who commented on PTO's proposals. We specifically stress the following basic points below:

a. The PTO has chosen remedies for its backlog problem that will not actually eliminate or even substantially reduce the backlog.

b. The PTO's effort to eliminate procedural options in the patent examination process would disproportionately and substantively harm our nation's most innovative companies.

c. The PTO fails to balance the potential costs and benefits of its proposals as required by Executive Order 12866, and ignores other options for addressing the backlog problems that could significantly lessen the likely negative impacts of the proposals on innovative businesses, while lessening the backlog problem.

d. Certain of the PTO's proposals are inconsistent with its statutory authority, or would run contrary to current law governing patents.

e. As the Small Business Administration, Chief Counsel for the Office of Advocacy, has reported, the proposed rules "will affect a substantial number of small entities," and "could severely weaken small entities' ability to protect their patents." Accordingly, PTO should "complete an [Initial Regulatory Flexibility Analysis pursuant to 5 U.S.C. § 603] prior to publication of the final rule." (*See* Tab G at 4) No such analysis was completed as part of the proposed rule.

In short, because the PTO's proposed changes in the patent process would fundamentally disadvantage innovative, entrepreneurial companies, the Innovation Alliance urges OIRA to return the rules to the PTO and Department of Commerce for further consideration and analysis of these highly consequential changes, the dramatic costs this rule could impose on some of the most critical components of our economy, and to further review alternative internal solutions.

Background on Patent Prosecution

It is fairly well known that a claim must be *new, useful* and *non-obvious* to issue in a patent. 35 U.S.C. §101. However, equally important, the claims must meet other statutory requirements. The specification must adequately disclose the claimed invention, and must also meet the *enablement, written description* and *best mode* requirements set forth in 35 U.S.C. §112. At present, inventors can submit claims in an original case, a Continuation Application (continuation, divisional or request for continued examination ("RCE")), a re-issue or re-examination as long as the above requirements have been met. These claims can be broadened at any time during the prosecution of a pending case and even for 2 years after issuance of a patent through a broadening re-issue application. This practice of drafting new claims during or after the pendency of an application has been approved by Congress and the Courts.[1]

The prosecution of applications before the PTO is a negotiation between inventors and the examiners. Each side has a set of tools with, and parameters in, which they operate. Inventors have the ability to continue the dialog with the patent office by filing and paying for additional Continuation Applications (or appeal if appropriate) as long as they make a bona fide attempt to advance the prosecution of the application. Examiners have a duty to review the applications and are measured most prominently by meeting their counts. For purposes of internal evaluation of patent examiners, the PTO utilizes what it calls a "count" system. The count system provides a patent examiner 1 count for the first "office action" on the merits of an application and 1 count for a disposal (*i.e.*, allowance, abandonment, examiner's answer to appeal, or RCE filing). Each type of Continuation Application has a place in the negotiation with the examiners.

RCE applications are typically used to continue a dialog that is progressing towards allowable claims. A typical scenario would be: (1) inventor files application; (2) examiner issues first office action; (3) inventor responds; (4) examiner issues a final office action; (5) inventor files a response to address the final office action; (6) examiner refuses to consider the final response and forces the filing of an RCE with a new filing fee and a preliminary amendment containing the same text as the after final response; and (7) the negotiation continues per the above.

It is important to note, that under present practice, inventors usually have one chance to respond to the examiner before filing an RCE. This limitation is important since the examiner can find and apply new prior art to the claims in the final office action and applicant will not have the ability to respond if they need to amend the claims in any way. Under the PTO proposed rules, such an RCE filing would prevent the inventor from filing another Continuation Application since her/his one Continuation Application has been used.

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[1] The Federal Circuit specifically explained that it is proper to draft new claims in continuation applications, even those that read on a competitor's product, as long as the other statutory requirements have been met:

> It should be made clear ... that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant. *Kingsdown Medical Consultants Ltd v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) (*emphasis added*).

This policy has been applied by the Federal Circuit numerous times and was not altered by Congress in either the 1995 and 1999 amendments to the patent law. It is worth specifically noting that the 1995 amendment eliminated "submarine" patents by creating a 20 year term from the original priority filing date instead of the existing 17 year term from the issue date of a specific patent (regardless of its claimed priority date). Even when making that significant change, Congress decided to leave untouched the above policy that has been and is applied in the Federal Circuit.

Continuations are generally used in three scenarios. First, if the PTO has allowed certain claims, but will not allow others, inventors often will have the PTO issue the allowed claims and will continue to argue about the rejected claims by filing a continuation containing those claims. Second, as the company continues to develop the invention, it may want to pursue new claims on the invention that are written in a different way or on different aspects of the invention to the extent they have become more economically significant (of course, such claims must be supported by the application as originally filed). Third, many companies choose to file one larger patent application for related inventions or to describe a product or system in a unified manner due to cost and other legal considerations, *e.g.*, best mode requirements and claim construction doctrines. The inventor/company selects which claims to pursue initially based on economic considerations, such as claim fees (*e.g.*, if the PTO forces the filing of a divisional then you end up paying for claims twice) or potential market size/success of the invention. It is important to note, that any such new claims cannot add new matter to the application and must meet the enablement and written description requirements mentioned above. It is further important to note, that most companies have a process to evaluate applications allowed by the PTO to determine whether a continuation should be filed. This process often looks at the economic value of the invention (now years after the original filing), the scope of the claim coverage compared to the present understanding of the prior art, and current posturing or potential disputes with other companies.

Continuation practice in the first instance above is designed to facilitate the negotiation between inventors and examiners while providing the inventor/company with some level of protection. In the second and third instances, inventors are voting with their wallets and specifically stating which claims and applications they believe are the most valuable. The continuation claims will generally, and rightfully, take a different approach to claiming the same invention (e.g., due to evolving case law) or claim another aspect of the invention that has not been claimed at this point (*e.g.*, small businesses often cannot afford to file all of the claims up front due to cost considerations and prefer to wait to see if they or their technology is successful before spending the additional time and money on the IP protection). The proposed rules would essentially kill these valuable patents.

Similarly with divisionals, at present applicants file groups of restricted claims serially in order to conserve costs and better understand the market and their companies' priorities before deciding whether to pursue a patent for each invention. According to PTO statistics, about 30% of all such restricted claim groupings are ever pursued by inventors. The order and whether to even pursue such a divisional is made again on economic grounds by the inventor. The proposed rules would force all such decisions to be made during the pendency of the original application and would likely result in filings that would never have been made since the failure to file eliminates any claim to such rights.

In all of the above situations the inventor is making a bona fide attempt to advance prosecution. There is nothing inherently bad about Continuation Applications, even Continuation Applications beyond the first one. Most of these cases are merely the result of internal PTO regulations (*e.g.*, the count system), the negotiation process that takes place between inventors and examiners, and the inventors desire to obtain the best and most complete claim coverage for their inventions. While there are undoubtedly some "abusive" continuation practices, the PTO has means to deal with those specific situations through prosecution history laches, disciplinary proceedings, or other means.[2] The PTO should not enact sweeping changes that will damage the innovation economy that is so important to the United States in order to address a bureaucratic problem it can solve with other available tools.

Shortcomings of the
January 3, 2006 Proposed Rule Packages

The PTO justified its rulemaking on two grounds. First, PTO has a backlog and feels the need to do something drastic. Second, the original claims provide a "public notice" purpose and that the economy should definitively know the scope of a patent right in the shortest time. The proposed changes will not help the backlog faced by the PTO. Furthermore, the public notice "policy" has been rejected by Congress and the Courts and is contrary to other available procedures available at the PTO (*e.g*., broadening re-issue applications). In addition, the proposed rules do not comply with Executive Order 12866 and contradict PTO's statutory authority and applicable case law.

Backlog Issues

Eliminating second and later continuations will have a negligible effect on the backlog. The PTO misleads the reader in stating that if they eliminated all Continuation Applications they would be able to reduce the backlog by issuing 35,000 more first office actions. This claim is misleading because the rule will not eliminate all continuations, but only a portion of second or later Continuation Applications (though the PTO's intent to eliminate all second and later Continuation Applications was fairly clear at the Town Hall meetings which were held in 2006). While Continuation Applications account for 117,000 of the 370,000 patent applications, second and later continuations account for less than 22,000 applications and further 50% of those 22,000 are RCE applications authorized by Congress in 1999. Comparing 10-15,000 applications (many which are legitimate continuations or divisionals) to the 450,000 new patent application filings the PTO expects in fiscal 2007, puts the potential effect of this proposed rule in its proper context when compared to the value and lost opportunity for inventors and companies to protect their valuable intellectual property rights (see below). There is an unsubstantiated assumption that a significant number of applications would not otherwise be filed without the availability of continuation practice.

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[2] Prosecution history laches as applied by the PTO was approved by the Federal Circuit in *In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002)*. In addition, the PTO Office of Enrollment and Discipline has authority over patent practitioners who must be registered with the PTO as a patent agent or patent attorney to practice before the office.

Even if all of these second and later continuations were eliminated, the backlog would continue to grow as inventors will instead be compelled to pursue one or more of the following options: 1) file more applications, including multiple applications with the same specification but different claim sets, or separate specifications directed to specific aspects of the invention; 2) file divisional applications much earlier during pendency of the original application with less certainty as to the value of such claims; 3) file more appeals, a procedure under which the PTO has finally gotten pendency under control; 4) file more petitions challenging final office action designations; and 5) petition for permission to file a continuation and appeal any rejections. These options will ad significant additional cost and have other negative consequences for inventors. The effect is that the PTO would move their burden to other procedural buckets, not eliminate or reduce its workload. None of this additional work was considered by the PTO in the proposed rules package and it would certainly overwhelm the predicted paltry effect of eliminating up to 22,000 of 450,000 applications expect to be filed in fiscal 2007.

"Public Notice" Rationale

The "public notice" function is a policy issue that has been decided already by the Courts and Congress. Furthermore, to the extent that the initial claim language rather than the original description is at issue, the alleged public notice function is illusory since most claims are amended during prosecution. In fact, access to the claims the PTO will eventually allow will likely be delayed in several ways: 1) appeals will take a long time so determination of the final scope of the claims that are more valuable will be delayed; 2) filing multiple applications to protect various claim sets based on one specification will make it more difficult for competitors or other to track related inventions because search engines and the available tools all create families of patents/applications based on priority claims; 3) the need to pursue all claims without the PTO issuing allowed claims while the inventor and examiner continue their negotiation will keep claims tied up for longer periods of time; and 4) the delays caused by petitions and appeals therefrom will cause delays in many applications for many applicants (as opposed to more directed reform that would only penalize "abusive" practices or bad actors.)

Bona Fide Attempt to Advance Prosecution

The PTO correctly focuses on two potential problem areas: 1) failure of the inventor to advance prosecution, *e.g.*, by maintaining placeholder applications, and 2) very poor direct filed foreign translation documents. The PTO has tools available to address these problem areas and does not need to upend the entire patent system and destroy significant future value in IP rights to do it. As stated above, the PTO has disciplinary procedures and the doctrine of prosecution history laches to address inventors or attorney's who fail to make a bona fide attempt to advance prosecution. Likewise, if the translation is so poor that the examiner cannot understand it, then it likely does not meet the requirements of 35 U.S.C. § 112 and should be rejected under those provisions with a careful review of any substitute specification that is filed or other substantial change to the specification to ensure that no new matter is added through such a filing or amendment.

In addition to the holes in the PTO rationale set forth in its proposed rulemaking, the standard for consideration of petitions to file a second or later continuation is essentially undefined. The PTO does not provide any example of when such a Continuation Application would be allowed and suggested at the public road show meetings that the standard would be high if not virtually impossible to meet. The standard put forward by the PTO is that the inventor must show "to the satisfaction of the Director that the amendment, argument, or evidence could not have been previously submitted." Attempts to advance prosecution by submitting amendments that the examiner refused to enter "will not by itself be a sufficient reason" to grant the petition. The standard of "to the satisfaction of the Director" is arbitrary and does not lend itself to a structured argument or appeal of such a rejection. Even though the PTO makes a point to mention advancing prosecution many times in the proposal, they use a standard for filing continuations that contradicts, and is completely devoid of any mention related to, advancing the prosecution of an application.

While there are undoubtedly "abusive" practices before the PTO, the proposed rules take a broad brush approach that will adversely affect legitimate activity and, furthermore, will not address the important backlog issue faced by the PTO. Under these rules, inventors acting in good faith would no longer be able to protect various aspects of their inventions based on the full and complete disclosure of their invention to the public through the patent process.

Failure to Adhere to Executive Order 12,866

The proposed rules would impose hundreds of millions of dollars of additional costs on inventors and could destroy billions of dollars in property rights and business value. Since these rules are admittedly "significant" under Executive Order 12866, the PTO must comply with the dictates of that order. It has not – the costs of the PTO's proposed rulemakings *significantly* outweigh any benefit to the system. PTO should be compelled to seek comment on a genuine and complete analysis of the costs and benefits of both rules before it can finalize either rule in any form. As currently proposed, both rules violate the principles articulated in Section 1, (b) (2), (3), (4), (6), and (11) of the Executive Order.

Cost-Benefit Analysis

The cost in reduced value of patents alone is probably in the billions of dollars, but this number is very difficult to quantify. An easier number to quantify is the need for additional work for new applications to either 1) draft claim sets which allow more flexibility as a case proceeds under the new rules, or 2) to respond to the request for claim designations under the Examination rulemaking. While there are other costs associated with these rules, such as the Examination Support Document, these two areas show how quickly the costs add up to the public. If one assumes 2 hours on average per new filing to create additional flexibility in the claims and specification (which is likely a gross underestimation), then the cost to consumers for the 450,000 new applications will be approximately $270 million (450,000 applications * 2 hours * $300 per hour). The cost to respond to the claim designations which need to be sent out for every case for which there is no office action, currently estimated to be 800,000 by the PTO, will easily be as much if not more. This enormous burden – greater than half a billion dollars to address some 20,000 second or later continuations annually – simply does not make sense, particularly since PTO already has adequate means to address these continuations without imposing significant new burdens on all applicants.

Alternatives

The PTO, to its credit, is taking other steps. The PTO, for several years, has been hiring almost 1000 new examiners per year and they plan to continue hiring more than 1200 per year for the next several years. While the PTO claims that it cannot hire its way out of the backlog situation, most patent practitioners believe that this should be a central part of the PTO plan to address the backlog. (*See* Tab A at 15, Tab C at 5, Tab F at 4) The PTO has also initiated or is involved in several other initiatives, such as a work from home program for examiners, a training academy for new examiners, retention bonuses for new examiners, and a peer-to-peer prior art review program. The effect of these changes is not known and it should be analyzed to understand the full effect of these changes in reducing the backlog before the PTO makes fundamental changes to the patent examination process that will prevent inventors from adequately protecting their inventions.

In addition, under Section 1 (b)(8) of the Executive Order, the PTO was obligated to "identify and assess alternative forms of regulation." The PTO must analyze potential alternatives, such as economic incentives or the many other suggestions in hundreds of critical comments. The PTO is a self-funding agency and the fees it charges are based on the cost to provide the services necessary to, among other things, review applications. If the PTO believes that second and later applications create "diminishing returns," then many other options are available to address that issue. A review of the extensive critical comments in the docket provides many avenues for consideration. At the very least, PTO should confer with Congress and consider charging higher fees for multiple continuations. This alternative and others were not addressed in the proposed rulemaking and therefore, we have to assume they were not considered. Such an approach would enable inventors who believe an invention has economic value worth the increased fees (which should be rationally related to PTO costs to provide the service or objectives to deter abusive behavior) to continue to pursue such applications and claims. In addition, the increased fees would make applications designed purely for delay more difficult to justify and the PTO would still have all of the other the tools discussed above to eliminate such practices. This financial approach to the problem provides an economic incentive to limit such applications and would provide a much less draconian result with fewer unintended consequences.

Contradictions with Statutory Authority and Caselaw

The PTO has not modified its own internal regulations that have led to the backlog problem; has incorrectly addressed the statutory concerns; and has not taken into account case law trends that necessitate certain behavior by patentees. The examiner count system which is a binary quantity system does not measure quality of the work by the examiners and encourages examiners to seek the filing of an RCE so that they can get 4 counts for a disposal. One way that examiners do that is to inappropriately designate office actions as final and refuse to accept any substantive response to the same. Inventors normally decide that it is easier to file an RCE than try to argue that an office action should not be final. This activity drives a significant number of RCEs, which were almost 50% of continuation filings according to the PTO statistics. Proactive management of examiners, modification of the count system, and enforcement of its existing rules would enable the PTO to substantially reduce RCE filings.

In 1995 Congress addressed late claiming in "submarine" patents by limiting the term of patent to 20 years from the earliest priority filing date as opposed to 17 years from issuance of the patent. Then, in 1999, Congress created RCEs to streamline prosecution of patents as part of the American Inventors Protection Act. At neither time did Congress choose to place a limitation on Continuation Applications generally or on the new RCE filings. The right and ability of applicants to file continuations is codified in 35 U.S.C. § 120, which reads in part:

> An application for patent for an invention disclosed in the manner provided by . . . section 112 of this title in an application previously filed in the United States . . . which is filed by an inventor . . . shall have the same effect, as to such invention, as though filed on the date of the prior application. (*Id.*)

In addition, the Federal Circuit has affirmatively approved of adding claims at a later time during prosecution as long as the claims are supported by the application language. *See Kingsdown*, 863 F.2d at 874. In addition, as the PTO points out, absolute limits on continuation are unlawful, however, the PTO proposed rules would effectively end multiple continuation practice. If the rules did not end this practice then the effect on the backlog would be even smaller and the cost benefit analysis would tilt further away from the proposal. The PTO should not be able to conduct an effective end run around the policy decisions of Congress and the Courts through these rules and should not be able to avoid the rulings that absolute numerical limits are unlawful by allowing continuation in an undefined type of case, for which no example currently exists.

The trends from the Federal Circuit case law are important to understand when addressing PTO's proposals. In recent cases, the Federal Circuit has held i) that anything not claimed is deemed dedicated to the public (*Johnson & Johnston Associates, Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046 (Fed. Cir. 2002) (*en banc*)), ii) significantly limited application of the Doctrine of Equivalents (*Festo Corp. v. Shoketsu K.K.K. Co.*, 324 F.3d 558 (Fed. Cir. 2000) (*en banc*)), iii) issued several decisions which have led to narrower claims interpretations, and iv) created a higher standard to demonstrate that claims are supported by the enablement and written description requirements mentioned above. These cases and other patent law trends have forced applicants to draft longer applications that deal with more alternatives and, to adequately protect their inventions, file more claims (often best advanced through continuation or divisional practice) on those alternatives and differing legal theories of infringement. The PTO did not analyze these trends in their proposed rule and the rules certainly will make obtaining adequate protection harder. In addition, both of the rules will be applied retroactively so that the continuation rules would actually prevent someone with a first continuation pending when the rules are enacted from filing another Continuation Application to adequately protect their invention. Applicant would have prepared and filed the application and prosecuted it with the examiner under the existing procedures and should not be retroactively subject to these draconian rules.

In addition, the Regulatory Flexibility Act generally requires an agency to publish an Initial Regulatory Flexibility Analysis whenever the Administrative Procedure Act requires notice and comment rulemaking. 5 U.S.C. § 603. As part of an IRFA, the agency must include a description and analysis of the numbers of small entities affected by the rule and a description of alternative approaches to address the impact on small businesses. While that requirement can be waived under some circumstances, those circumstances are not fairly present here. Indeed, in written comments, the Chief Counsel for Advocacy of the Small Business Administration has commented that "the rule will affect a substantial number of small entities" and has urged the PTO to complete an IRFA. *See* Tab G at 4. The PTO has not done so.

Unintended Effects of the Proposed Rules

As many practitioners have stated in their comments, the PTO proposed rules will not promote innovation, but instead may stifle it. The rules will make obtaining proper coverage for the most important inventions very difficult, if not impossible. This in turn, makes it more difficult for those companies dependent on patents, such as small innovative technology companies, to raise capital and do business with larger established companies in the market. As stated above, by filing additional continuations, inventors are speaking with their wallets, by allocating scarce time and money to only the most valuable and important assets. Less than 2% of patents end up in litigation or other disputes, which leads many to believe that the majority of patents have limited value. It is true that a small number of patents have large economic value and/or impact on society. It is these more significant patents that will be harmed by these proposed rules. Based on that alone, the proposed rules will harm innovation since entrepreneurs are less likely to create companies to pursue ideas without the availability of adequate forms of protection and venture capitalists are less likely to fund such companies, and so on. For these reasons, the proposed rules would substantially and disproportionately harm America's most innovative and entrepreneurial businesses.

Support for the proposed rules seems to be concentrated among a few very large companies with huge patent portfolios. While PTO's regulatory changes may benefit this select few, they will cause serious harm to smaller companies trying to bring innovative products and technology into the market. It will benefit these larger companies with established portfolios because they have the existing patents crafted under the old rules, their exposure to infringement claims will be reduced, sheer numbers of patents are more important that quality patents for many of such companies, the harm to their portfolios will be smaller as a percentage of their overall portfolio, and they have the money to pursue patents in parallel on key technologies. All of these characteristics are missing for new and/or small companies. Therefore, the rule changes appear to be designed to fix a perceived abuse problem affecting more mature technology, but will most significantly effect "white space" innovations, the developers of which need the flexibility provided by continuation practice to protect their innovations.

Most of our comments have focused on the Continuation Rule, however, the Claim Examination Rule also presents significant issues. Most significantly this rule makes continuations more likely, by making final office actions easier for examiners to issue. Examiner's will have to examine only up to 10 initial claims, but if an inventor needs to amend its claims to include a restriction from one of the non-elected dependent claims then the examiner must conduct a new search and a final office action would be proper. By contrast, final office action would not be proper under present practice if an inventor merely incorporated the limitations from a dependent claim into an independent claim. Together, the two proposed rules would 1) limit the examination of the initial claims, thereby greatly increasing the need for continuations, while 2) essentially eliminating continuations. As is evident, the combination of these two proposals will make matters much worse. While there are other issues and concerns created by this rulemaking, this one is the most important.

Conclusion

For the reasons stated above, we ask OMB to return these two proposed rules packages to the PTO for reconsideration.

Innovation Alliance Comments to OMB

Derek Minihane

Unintended Consequences

- This “procedural” rule change will have substantial negative substantive impact on inventors ability to protect their intellectual property through patents
- There were hundreds of comments submitted – most were negative
  - Patent Public Advisory Committee
  - National Institutes of Health
  - Intellectual Property Owners (IPO)
  - ABA, IP Section
  - District of Columbia Bar, PTC Section
  - AIPLA

Quick Overview – Proposed Rules

- The changes will not reduce the PTO backlog
- These “fixes” to the patent examination process will disproportionately and substantively harm our nation’s most innovative companies
- Potential costs and benefits are not properly balanced as required by Executive Order 12866
- Other options for addressing the backlog problems with significantly less potential to negatively impact innovative businesses have not been adequately considered
- Inconsistent with statutory authority and/or contrary to current law governing patents
- According to Small Business Administration, Chief Counsel for the Office of Advocacy, a complete Initial Regulatory Flexibility Analysis pursuant to 5 U.S.C. § 603 prior to publication of the final rule was not completed

Agenda

- Patent Prosecution Backgrounder
- Shortcomings in Proposed Rules Support Document
- Failure to Adhere to Executive Order 12866

Patent Prosecution Backgrounder

Patent Requirements

- 35 USC 101
  - New
  - Useful
  - Non-obvious
- 35 USC 112
  - Enablement
  - Written Description
  - Best Mode

Prosecution Practices

- Prosecution is a negotiation with the examiner
  - RCE enables this negotiation
- If supported by the disclosure, the inventor can add new or modify existing claims
  - Continuation practice
- Restricted claims can be pursued serially in order or economic priority
  - Divisional practice

- PTO examiner count system
  - 1 count for the first office action
  - 1 count for “disposal” (i.e., allowance, abandonment, examiner’s answer to appeal, or RCE filing)

RCE Practice

- Typical case proceeds as
  - First Office Action
  - First Response
  - Final Office Action
  - Response NOT Considered
  - File RCE
  - Preliminary Amendment
  - First Office Action
  - Etc.
- Often 1 substantive response before filing an RCE
- RCE filing bars filing a continuation under the proposed rules

Continuation Practice

- PTO allowed some claims, but rejected others
  - Inventors often take the allowed claims and file a continuation to pursue others
- Increased economic significance of an invention
  - Companies and inventors review allowed applications in light of economic value of the invention, scope of prior art, scope of claims and current competitive situations to determine whether more claims are warranted
  - Inventors vote with their time and money
- Obtaining full coverage for complex inventions
  - Often better to file related inventions in one application
  - Cost considerations for filing all claims at start
  - Continuations allow efficient allocation of resources

Continuation Practice

- It should be made clear ... that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant (emphasis added). *Kingsdown Medical Consultants Ltd v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988)
- Policy not modified by Congress in 1995 or 1999 amendments to the patent laws
  - In 1995 Congress changed the term of patent rights
  - In 1999 Congress added the RCE application

Divisional Practice

- Presently applicants can determine the economic value of claims restricted in existing applications and decide which to pursue first
  - Conserve PTO and applicant resources
  - PTO states that only 30% of restricted claim grouping are ever pursued
  - Proposed rule would force all filings “at once”, i.e., during the pendency of the first filing

Shortcoming in the Proposed Rules Support Document

The Numbers Do Not Add Up

- PTO claims it could have reduced the backlog by 35,000 cases if no continuations were filed
  - Misleading since the rule allows continuations
  - Continuations made up 117,000 of the 360,000 applications filed according to the rules package
    - Less than 22,000 of the 117,000 would be affected by rule
    - Half of those are RCEs
    - Second and later continuations represent perhaps 10-15,000 of the expected 450,000 new filings in fiscal 2007
- Backlog will probably get worse, no analysis of
  - surge in new filing strategies by inventors
  - surge in divisional filings due to new rule
  - petition filings and increased appeals

Bona Fide Attempt to Advance Prosecution

- PTO rightly states that applicants have a duty to make a bona fide attempt to advance prosecution
  - The proposed rules are arbitrary and do not attempt to address this concern
  - The proposed rules actually prevent Continuation Applications that are a bona fide attempt to advance prosecution
  - The standard for allowing a second or later continuation is not tied to this policy
- Existing rules allow the office to deal with “abusive” filings, which are an issue
  - Prosecution history laches
  - Office of Enrollment and Discipline

Exemplary Problems

- Poor “direct filed” translations of foreign cases
  - More narrow targeted reforms or proposals could be used to address this issue,
    - Section 112 enablement requirement
    - Review of amendments for “new matter”
- Placeholder applications maintained for the purpose of adding claims later may not advance prosecution
  - PTO has tools to address these type of filings
- Resolving these legitimate issues does not require substantively changing the patent prosecution process for all inventors
  - These changes will harm the innovation economy

Undefined Standard

- Permission to file a second or later continuation requires “a showing … that the amendment, argument, or evidence could not have been submitted during the prosecution of the prior filed application”
- A new amendment “will not by itself be a sufficient reason to warrant grant of a petition”
- The standard allows arbitrary action by the Director and is too high as explained by the PTO as the Town Hall meetings
- In the various public meetings I attended on the proposed rules, the PTO did not define any scenario under which a petition would be granted

- The standard should be tied to applicants making a bona fide attempt to advance prosecution

Failure to Adhere to Executive Order 12866

Overview

- Proposed rules will impose hundreds of millions of dollars of cost on patent applicants
- Unintended consequences and negative substantive impact will likely destroy billions of dollars in intellectual property rights and business value
- PTO has admitted the rules are “significant” under Executive Order 12866, but has not complied with the dictates of that order

Cost-Benefit Analysis

- Cost to comply will be greater than half a billion dollars (>$500,000,000)
  - Very conservative estimate
  - 2 hours added to applications for claim flexibility
  - 1 hour on average to select claims for Examination Rule
  - Does not take into account Examination Support Documents
- Affect on backlog will be negligible or completely non-existent
- PTO has adequate remedies to deal with any existing abusive continuation practices

Retroactive Impact is Severe

- Proposed rule will apply to any new continuation
  - If a case filed under the existing regulations already has one (1) Continuation Application, then no new continuation or RCE would be allowed without the petition process
  - Applicants have been operating under existing rules in filing applications and building portfolios
    - Rules should at least have a transition period, such as any case filed before the date of the rules would be considered the “original” application for purposes of any limitations
    - Retroactivity will require large expense this year in review and filing of new applications before rules go into effect
    - New filings to avoid retroactive impact will negatively affect the PTO backlog

Alternatives

- Internal PTO changes have not been adequately factored into the equation
  - 1000+ new hires per year for several past years and into the near future
  - Other initiatives, include work from home, training academy, retention bonuses, peer-to-peer review
- Economic incentives have been overlooked
  - PTO fees are based on the cost to provide the service
    - Users supported 20-30% fee increases a few years back to enable the PTO to staff up and implement new initiatives
    - Congress has ended fee diversion, at least for now
  - If the costs is higher, fees should be raised appropriately
  - Many comments proposed a graduated scale for later continuations to discourage abuse and focus them on truly economically significant patents

Contradictions with Internal Regulations

- PTO count system (2 per "disposal") contributes significantly to RCE and divisional filings
- Proactive examiner management and enforcement of existing rules and standards would reduce RCEs, for example,
  - Examiner's inappropriate final office actions and refusal to respond to same
- Application of Unity of Invention standard would limit divisional filings
  - Combine prosecution of method and apparatus claims
- No attempt has been made to address these underlying causes of the backlog

Contradictions with Statutes

- 35 U.S.C. 120, which codified longstanding practice, states in part:

  An application for patent for an invention disclosed in the manner provided by … section 112 of this title in an application previously filed in the United States … which is filed by an inventor … shall have the same effect, as to such invention, as though filed on the date of the prior application.

- Congress has not limited inventors ability to claim priority under Section 120 through two recent amendments to the patent laws
  - In 1995, Congress changed patent term from 17 years from patent issuance to 20 years from the first priority date
  - In the 1999 American Inventors Protection Act Congress added RCE practice
  - There are no such proposals in the current proposed legislation

Contradictions with Caselaw

- The Federal Circuit caselaw has approved
  - Applicants ability to file claims in continuations that are supported by the original application
  - Prosecution history laches to penalize applicants that do not attempt to advance prosecution
- Federal Circuit continues to issues cases that require longer more detailed specification and more, not less, claims
  - Dedication of unclaimed matter to the public, *Johnson*
  - Limiting doctrine of equivalents, *Festo*
  - Trend to more narrow claim construction
  - Tougher application of the written description and enablement requirements

Unintended Consequences

- The rules make obtaining adequate and complete claim coverage very difficult, especially for complex inventions
- The rules will harm small innovative companies that are more dependent on strong patents to
  - negotiate agreements with large, established companies
  - raise capital to fund R&D and expansion
- Continuations represent most economically valuable patents as determined by inventors themselves
  - Inventors continue to spend time and money for applications that have economic value
  - PTO asserts that continued examination “suffers from diminished returns” even though inventors clearly disagree with the spending of their limited resources (time and money)

Disparate Effect of Rules

- The rules are supported by large established companies with mostly large patent portfolios
  - For example, Intel, Micron, Apple, Microsoft
- The rules will benefit these companies at the expense of new growth companies
  - Existing portfolios benefited from current continuation practice
  - Rules will reduce their exposure to patents since companies will not be able to obtain complete claim coverage for inventions
  - Sheer numbers of patents are more important to many of these companies
  - The harm as a percentage of their portfolio will be less
- Workarounds of the rules will be prohibitively expensive for small business and small inventors
  - Filing all possible claims in initial case
  - Filing many applications instead of one complete disclosure
  - Pursuing all divisional applications during pendency of the original application

Small Business Impact

- Regulatory Flexibility Act generally requires an agency to publish an Initial Regulatory Flexibility Analysis whenever the Administrative Procedure Act requires notice and comment rulemaking. 5 U.S.C. § 603.
- As part of an IRFA, the agency must include a description and analysis of the numbers of small entities affected by the rule and a description of alternative approaches to address the impact on small businesses.
- In its written comments, the Chief Counsel for Advocacy of the Small Business Administration has commented that "the rule will affect a substantial number of small entities" and has urged the PTO to complete an IRFA.

Examination Rules Compound the Problems

- Limits the number of claims the PTO will substantively search
  - Makes final office actions more likely
  - Therefore makes RCE and continuations more likely
- When added to the continuation limitations above, it makes all of those issues addressed worse